(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
11 January 2007 (11.01.2007)

PCT

(10) International Publication Number
WO 2007/006000 A2

(51) International Patent Classification:
A61B 18/14 (2006.01)

(21) International Application Number:
PCT/US2006/026321

(22) International Filing Date: 6 July 2006 (06.07.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
11/176,803 6 July 2005 (06.07.2005) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 2007/006000 A2

(54) **Title:** FUSE-ELECTRODE ELECTROSURGICAL APPARATUS

(57) **Abstract:** An electrosurgical apparatus for performing a surgical procedure on a target site, comprising a shaft having a distal end portion, the distal end portion comprising an active electrode including a fuse leg or portion, the fuse leg adapted to break and disable the instrument upon applying a voltage differential between the active electrode and a return electrode for a predetermined amount of time, hi another embodiment, the present invention is a method of performing an electrosurgical procedure on a target tissue, comprising: placing an electrosurgical instrument in close proximity to the target tissue, the electrosurgical instrument comprising an active electrode having a pre-selected portion adapted to break and disable the instrument upon applying a voltage differential thereto for a working time; and applying the voltage differential.

FUSE-ELECTRODE ELECTROSURGICAL APPARATUS

BACKGROUND

Field of the Invention

This invention relates to an electrosurgical apparatus, in particular an electrosurgical apparatus comprising an electrode assembly including an electrode leg or portion adapted to break and disable the apparatus upon expiration of a predetermined amount of use of the apparatus.

Description of the Prior Art

In various electrosurgical instruments, as illustrated for example in Figure 1, a voltage difference may be applied between an active and return electrode to treat a target tissue such as cartilage. The tissue may be immersed in an electrically conductive fluid. The electrically conductive fluid may be supplied from the device itself, a separate device, or it may be already present in the body or cells. Treatment may include, for example, ablating, heating, cutting, removing, puncturing, probing, and otherwise stimulating tissue at the target site. The target site may include any part of a patient's body including, for example, the skin, knee, nose, spine, neck, hip, heart and the throat. See, for example, U.S. patent No. 6,149,620 and U.S. patent application No. 09/457,201 which are hereby incorporated by reference in their entirety.

In treating a target site, an important consideration is to limit the time that the tissue is exposed to current so as to avoid unintended damage to the tissue. Another consideration is to prevent accidental reuse of disposable components of the instruments, such as the electrodes, to reduce the risk of infection. A further consideration is to avoid using an instrument having electrodes that are worn or eroded to a state such that their mechanical structures are weakened to an unacceptable level and are likely to break.

One approach to limit exposure of the tissue to excessive current, and or control wear on the electrode is to rely on the operator to monitor the time that the instrument is in use and stop treatment at an appropriate time. This may be done, for example, either manually or automatically using various timing devices on the power supply.

However, while monitoring the power supply is feasible to track the time that the tissue is exposed to current, merely monitoring the power does not indicate to the operator the extent of erosion and wear occurring on the electrodes. Further, depending on the material used, the dimensions of the active electrode, the type of conductive fluid used, the location of the connection to the power supply and the voltage applied to the electrodes, erosion may occur to the extent where the electrodes undesirably breaks causing bits of fragments to become lodged in the tissue. Thus, while it is possible to monitor the power to prevent over-exposure of the tissue to current, it is desirable to decide when to stop use of the instrument to avoid excessive erosion and wear on the electrodes.

Another approach to monitoring the instrument for electrode erosion and wear is to visually check the physical condition of the electrodes. A problem with this approach is that because the electrodes are almost invisible to an unaided eye, it very difficult to visually determine erosion and wear. A further practical problem is that during the exigencies of a surgical procedure, a practitioner may overlook the need to periodically check the electrodes for erosion wear in time to stop using the instrument before wear becomes a problem and or the electrode breaks.

Accordingly, there is need for a more reliable way to prevent unintended and or prolonged use of the equipment, excessive exposure of the tissue to current, the consequences of a deteriorated electrode, and or the unintended reuse of disposable components of the instrument.

SUMMARY OF THE INVENTION

An electrosurgical apparatus for performing a surgical procedure on a target site, comprising an active electrode assembly including a fuse leg or feature adapted to break and disable the apparatus upon expiration of a predetermined amount of use of the apparatus. In one embodiment the electrosurgical instrument, comprises a shaft having a distal end portion, the distal end portion comprising an active electrode including a fuse leg, the fuse leg adapted to break and disable the instrument upon applying a voltage differential between the active electrode and a return electrode for a predetermined amount of time. In another embodiment, the present invention is a method of performing an electrosurgical procedure on a target tissue, comprising: placing an electrosurgical instrument in close proximity to the target tissue, the electrosurgical instrument comprising a return electrode, and an active electrode having a pre-selected portion adapted to break and disable the instrument upon applying a voltage differential between the active and return electrodes for a working time; and applying said voltage differential.

Advantageously, with the present instrument and method, a target tissue may be treated with reduced risk and consequences of a random instrument failure since the instrument is adapted to fail upon expiration of a predetermined amount of use. The break in the electrode is at a predictable location after a predetermined amount of time.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of an electrosurgical apparatus in accordance with an embodiment of the invention.

Fig. 2 is a side view of a target site in a patient being treated by an electrosurgical apparatus in accordance with an embodiment of the invention.

Fig. 3 is a perspective view of the distal end an electrosurgical apparatus with an intact active electrode in accordance with an embodiment of the invention.

Fig. 4 is a perspective view of the distal end an electrosurgical apparatus with an eroded active electrode in accordance with an embodiment of the invention.

Fig. 5 is a perspective view of insulator adapted for receiving an active electrode in accordance with an embodiment of the invention.

Fig. 6 is a perspective view of an active electrode being installed on an insulator in accordance with an embodiment of the invention.

Fig.7 is a perspective view of an active electrode in accordance with an embodiment of the invention.

Fig. 7A is a partial view of another embodiment of the present invention showing an active screen having a wear feature.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

With reference to Figure 1, an electrosurgical instrument (10) is shown for performing a surgical procedure on a target site. The surgical procedure includes volumetric removal of soft tissue from the target site, for example volumetric removal of soft tissue in the throat as illustrated schematically in Figure 2, or soft tissues at other target sites including the skin, knee, nose, spine, neck, hip, and heart.

In one embodiment as shown schematically in Figures 3 and 4, the instrument comprises an active electrode assembly (12) located at the distal end (18) of a shaft (14) and includes a fuse leg (16a) sized to preferentially erode and break before a break occurs on any of the anchor legs (16b and 16 c) upon expiration of a predetermined amount of use of the instrument.

In another embodiment, the invention is a method of performing an electrosurgical procedure using the instrument such that the procedure is automatically stopped after a predetermined amount of use of the instrument,

due to failure on the fuse-electrode leg. In various embodiments, a predetermined amount of use includes tracking the accumulative current passing through the electrode assembly while treating a target site, as well as anticipating the erosion and wear on the fuse leg and designing the leg using appropriate materials and dimensions such that the leg will break upon a predetermined amount of use. In another embodiment, anticipation of a break on the fuse leg includes designing and adapting the leg based on the operating voltage and the conductive fluid in contact with the electrodes.

In particular the applicant by designating a portion of the active electrode as a fuse leg, and selectively choosing the material, the operating voltage, the conductive fluid, and sizing the designated leg to conduct current through the electrode, the applicant can predetermine the location and time that the instrument shall be disabled.

While not intending to be bound by theory, it is believed that erosion and wear are attributable to an electrochemical action on the electrode due in part to the presence of a conductive fluid at the target site, and the passage of a current through the electrode in the presence of this conductive fluid. In particular, during use of the instrument, as a result of the current passing through the conductive fluid and the electrodes, plasma is formed in the vicinity of the electrodes when a voltage difference is applied between the electrodes. The plasma appears to cause wear on the electrode.

In one embodiment an active electrode assembly (12) as illustrated in Figures 3, 4 and 6, is made of a conductive material such as platinum, tungsten, molybdenum, titanium, and corrosion resistant stainless steel. In this embodiment, the active electrode comprises a fuse leg (16a), and one or more anchor legs (16a, 16b) that together support the electrode assembly (12) on the insulator (22).

In various embodiments, the fuse electrode leg (16a) is the input path for current into the electrode assembly, and is thus electrically connected to a high frequency voltage source (not shown). To selectively promote erosion and wear on the fuse leg, several factors are controlled including: the material of the electrode, the dimensions of the electrode, the shape of the electrode, the range of voltage applied to the electrode, and the number of fuse and anchor legs. Further, it will be appreciated that the shape of the electrode assembly may vary and may take the form of a screen, a wire loop or another suitable shape; similarly, the cross-section of the electrode may vary and can be circular, cylindrical, square, oblong, disc, and or variations of these shapes.

In one embodiment the dimension of the fuse leg is selected for a width of about 0.008 inch to 0.015 inch, and a thickness of about 0.004 to about 0.007 inch. For this range of dimensions, a suitable operating voltage is about 50 volts to about 1000 volts, in particular about 200 volts to 350 volts. However it will be appreciated by one skilled in the art that in view of the description, these parameters may be varied to achieve a particular design. Similarly, the choice of material can vary; for example, a material such as platinum, tungsten, molybdenum, titanium

and corrosion resistant stainless steel may be used. Similarly, the design is influenced by the desired operating time of the instrument which may vary from about 2 minutes to about 30 minutes or to about 7 minutes to about 10 minutes depending the procedure used, the amount of contact that the electrode makes with the tissue, and the conductive fluid (such as, e.g., saline and lactated ringers solution).

Desirably, anchor-legs (16b, 16c) are larger than the fuse-electrode leg (16a), however as is illustrated in Figure 5 and 6, the actual size of each type of legs is constrained by the physical limitations of the electrode assembly (12), and the surface area (24) on the insulator to receive the electrode assembly. In designing the fuse leg to be smaller than the anchor legs it will be recognized by one skilled in the art that the fuse leg will generate a higher current density than a current density on any of the anchor legs and therefore will desirably erode at a faster rate than the anchor legs during use.

In various embodiments, the size, location, material of the fuse leg, the presence of a conductive material and the intended use of the instrument are factored together to optimize the design. Regarding size, in one embodiment a properly placed tungsten fuse of width 0.10 inches and thickness 0.007 inches will have a useful life of 7-10 minutes. Regarding location, in one embodiment the fuse leg is located in a position more likely to wear such as where power is inputted to the electrode or where the electrode is more likely to come in contact with tissue, or where the electrodes is located close to a suction lumen. On the other hand, examples of positions where the electrode is less likely to wear are those regions centrally located (most dispersed) from the return electrode, regions protected from high fluid velocity streams, and region not generally in constant contact with tissue during normal use.

As illustrated in Figures 3 and 4, the before-and-after effects of designing the fuse-electrode leg (16a) in accordance with the invention can be seen, for example in Figure 3 which depicts an intact active electrode assembly (12) anchored onto the insulator (22) prior to using the instrument, and Figure 4 which depicts the active fuse electrode (16a) after it has been eroded and broken, while the anchor electrodes (16b and 16c) are still intact. In the embodiment shown in Figures 3-6, an active electrode assembly having a fuse-electrode leg is configured to disable the instrument after a predetermined amount of use.

In one embodiment as shown in Figures 3-6, insulator (22) is formed of a ceramic material that defines holes (24a, 24b and 24c) in the surface for receiving fuse-electrode leg (16a) and anchor-electrode legs (16b, 16c). Additionally, insulator defines an axial aperture (26). Fluid may be supplied or aspirated from aperture (26).

In one embodiment, as shown in Figure 1, the shaft (14) includes an axial lumen (30) opened at said distal end (32) of the shaft . In this embodiment as illustrated in Figures 3, 4 and 6, the electrode assembly (12) comprises

openings in the form of a sieve for restricting passage of materials into the lumen resulting from ablation of tissue at the distal end of the shaft (14).

In an embodiment illustrated in Figure 1, shaft (14) further comprising an aspiration tube (32) disposed partly on the shaft for aspirating material away from the distal end. Also illustrated in Figure 1 is a fluid supply system disposed (34) on the shaft for supplying conductive fluid to the distal end. Examples of aspiration tubes and fluid supply systems that are useable with the present apparatus are described in U.S. patent No. 6,149,620, and U.S. patent application No. 09/457,201, supra, and incorporated herein by reference.

As illustrated in the embodiments of Figures 3 and 4, return electrode (20) is provided on the shaft (14), for completing the electrical connection to the voltage supply. However, return electrode may be positioned elsewhere on the shaft, on another device, or on an external pad.

In another embodiment, the invention is a method of performing an electrosurgical procedure on a target location using the present apparatus. In one method the procedure involves placing the instrument at a target location, and treating the target tissue with the electrode assembly until a failure at the fuse-leg disables or electrically shorts the instrument. In the method, treatment includes applying a high frequency voltage to the electrode assembly to facilitate failure at the fuse-leg during the procedure.

Using the above described instrument, tissue may be ablated, punctured, cut, coagulated, etc. Depending on the tissue being treated, in one procedure a voltage of about 50 volts to 1000 volts can be applied; in other procedures, a voltage in the range of 200 volts to 350 volts can be applied. Also, depending on the tissue, treatment may last up to about one hour; in other procedures, treatment is about 2 minutes to about 30 minutes, more narrowly in the range of about 7 to 10 minutes. In various embodiment treatment may also include directing a conductive fluid to the target tissue.

Figure 7 illustrates another embodiment of the present invention. Figure 7 shows a distal end 100 of an electrosurgical instrument. The distal end comprises an active electrode in the shape of a screen 110. Screen electrode includes a plurality of openings 115. The openings may take a wide variety of shapes such as, for example, triangles, rectangles, squares, circles, or another geometry that allows passage of fluid there through.

The active electrode 110 is attached (and electrically connected) to a voltage supply via wires. The wires have heads in the shape of spheres or balls 130. Extending from the balls 130 into the insulator are wires (not shown). A voltage difference is applied between active electrode and a return electrode to modify a target tissue in the vicinity of the active electrode. The invention is also adapted to cause ablation of tissue in the presence of an electrically conductive fluid as described above.

As shown in Figure 7, the active electrode may have a portion that is adapted to disintegrate more quickly than other portions of the active electrode. In the electrode shown in Figure 7, portion 140 is adapted to selectively decompose or disintegrate. Portion 140 is a sacrificial link in a sense. When all current or electrically communication from the voltage supply is provided solely through the ball wire associated with wear feature 140, an electrical short occurs as soon as wear feature 140 disintegrates beyond ball wire 120 (not shown). The other ball wires or structure, however, continue to hold the active electrode to the insulator. Accordingly, the device is disabled in a manner that prevents any part of the active electrode from inadvertently detaching from the device.

It is believed that wear feature disintegrates selectively and more quickly than any of the other arms on the active electrode because wear feature 140 provides a higher current density and thus, increased disintegration at this location on the electrode. A number of different geometries may be provided to provide a predictable wear portion. Indeed, a small, narrow, bridge may join ball wire 120 with the active screen as shown in Figure 7A. Also, the bridge may taper abruptly, or smoothly with slight curvature.

Additionally, the active electrode, fuse leg, connectors, may be integrated together or may be formed of one integral unit. Alternatively, each of the components may be attached or connected to form a functional unit.

While the invention is described with reference to the present Figures and methods, it will be appreciated by one of ordinary skill in the art that features of different embodiments may be combined for a particular instrument and or procedure in accordance with the present invention. Thus, alternative combinations are to be considered to be within the scope of the present invention unless one feature or aspect mutually excludes the other. Accordingly, the scope of the invention should not be limited to the embodiments as described herein, but is limited only by the scope of the appended claims.

CLAIMS

What is claimed is:

1. An electrosurgical apparatus for performing a surgical procedure on a target site, comprising an active electrode assembly including a fuse leg adapted to break and disable said apparatus upon expiration of a predetermined amount of use of said apparatus.

2. The electrosurgical apparatus of claim 1, wherein said break is controlled by optimizing a parameter selected form the group consisting of a dimension of said fuse leg, a voltage applied to said fuse leg, a material comprising said fuse leg, and a conductive fluid in contact with said fuse leg.

3. The electrosurgical apparatus of claim 2, wherein said dimension of said fuse leg is preferably a width of about 0.008 inch to 0.015 inch, and more preferably a thickness of about 0.004 to about 0.007 inch.

4. The electrosurgical apparatus of claim 2, wherein said high frequency voltage preferably is about 50 volts to about 1000 volts, and more preferably about 200 volts to 350 volts.

5. The electrosurgical apparatus of claim 2, wherein said material is selected from the group consisting of platinum, tungsten, molybdenum, titanium and corrosion resistant stainless steel.

6. The electrosurgical apparatus of claim 1, wherein said predetermined use is about one hour, preferably about 2 minutes to about 30 minutes, and more preferably about 7 minutes to about 10 minutes.

7. The electrosurgical apparatus of claim 1, wherein said active electrode assembly comprises one or more anchor legs, and herein said anchor legs include said fuse leg.

8. The electrosurgical apparatus of claim 9, wherein said fuse leg is adapted to break before any of said anchor legs break and wherein said fuse leg is adapted for a higher current density compared the current density on said anchor legs.

9. The electrosurgical apparatus of claim 1, further comprising a high frequency voltage generator for supplying current to said electrode assembly.

10. The electrosurgical apparatus of claim 1, further comprising:

a shaft having a distal end wherein said electrode assembly is disposed on said distal end;

a return electrode disposed on said shaft proximally to said electrode assembly; and

an insulator positioned between said return electrode and said electrode assembly for electrically insulating said return electrode from said electrode assembly.

11. The electrosurgical apparatus of claim 12, wherein said electrode assembly and said fuse leg comprise an active electrode.

12. The electrosurgical apparatus of claim 12, wherein said fuse leg is partially embedded in said insulator.

13. The electrosurgical apparatus of claim 12, wherein said shaft defines an axial lumen opened at said distal end of said shaft.

14. The electrosurgical apparatus of claim 12, further comprising an aspiration tube disposed partly on said shaft for aspirating material away from said distal end.

15. The electrosurgical apparatus of claim 12, further including a fluid supply system disposed partly on said shaft for supplying conductive fluid to said distal end.

16. An electrosurgical instrument, comprising: a shaft having a distal end portion, said distal end portion comprising an active electrode including a fuse leg, said fuse leg adapted to break and disable said instrument upon applying a voltage differential between said active electrode and a return electrode for a predetermined amount of time.

17. The electrical instrument of claim 16, further comprising one or more anchor legs for securing said active electrode assembly on said shaft.

18. The electrical instrument of claim 17, wherein said fuse leg is dimensioned to break before any of said anchor legs break.

19. The electrical instrument of claim 16, wherein a return electrode is positioned on said shaft proximally to said active electrode; and

an insulator is interposed between said return electrode and active electrode on said shaft for electrically isolating said return electrode from said active electrode.

20. The electrosurgical apparatus of claim 16, further including a high frequency voltage supply electrically connected to said fuse leg.

21. A method of performing an electrosurgical procedure on a target tissue, comprising:

placing an electrosurgical instrument in close proximity to said target tissue, said electrosurgical instrument comprising a return electrode, and an active electrode having a pre-selected portion adapted to break and disable said instrument upon applying a voltage differential between said active and return electrodes for a working time; and applying said voltage differential.

22. The method of claim 21, wherein said voltage differential is in a range of about 50 volts to about 1000 volts.

23. The method of claim 21, wherein said voltage differential is applied for about one hour, preferably about 2 minutes to about 30 minutes, and more preferably about 7 minutes to about 10 minutes.

24. The method of claim 21, wherein said pres-selected leg comprises a width of about 0.005 inch to about 0.125 inch.

25. The method of claim 21, wherein said electrosurgical procedure includes ablating said target tissue.

26. An electrosurgical instrument, comprising: a shaft having a distal end portion, said distal end portion comprising an active electrode including a wear feature, said wear feature adapted to disintegrate and disable said instrument upon applying a voltage differential between said active electrode and a return electrode more than a predetermined amount of time.

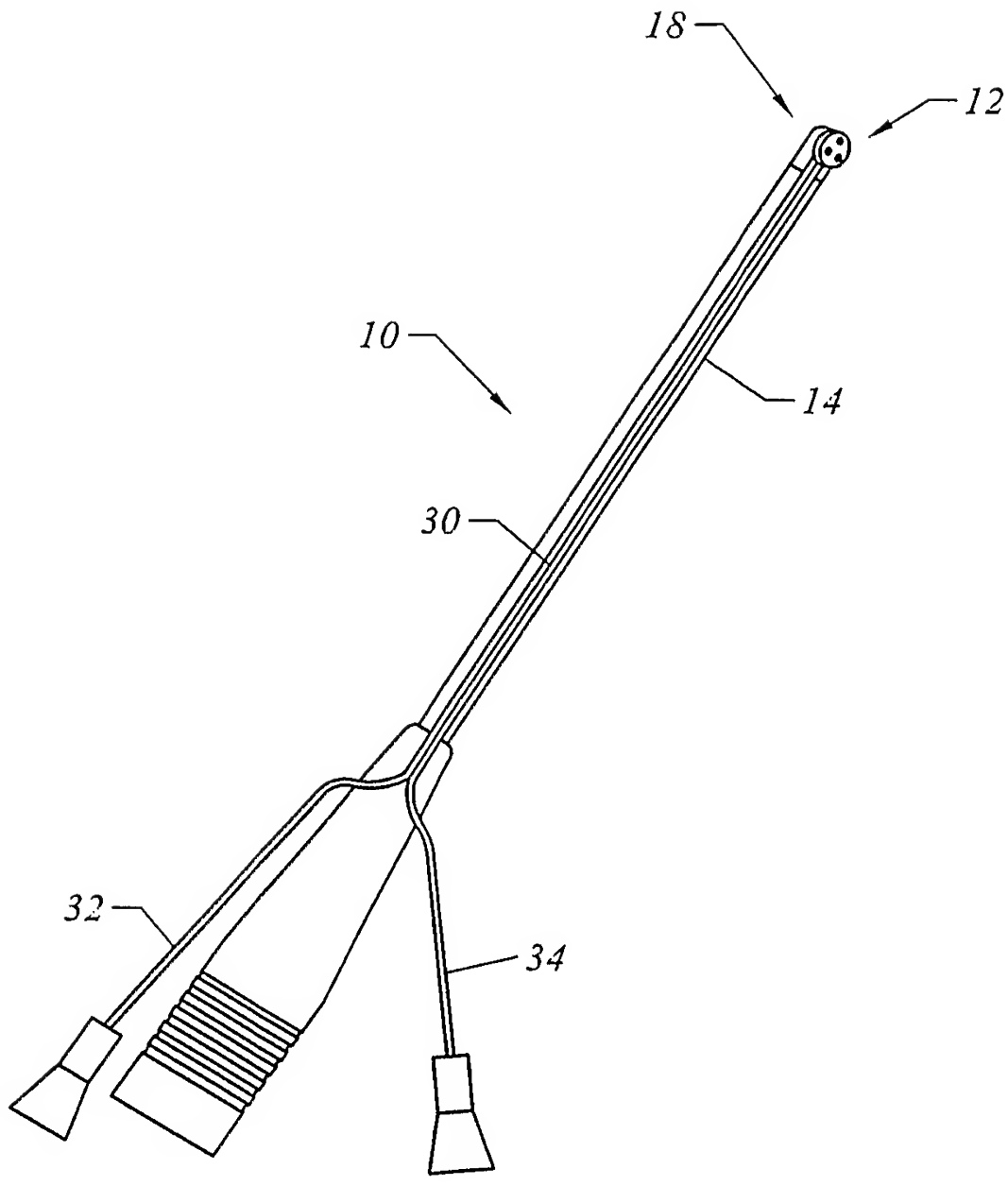

FIG. 1

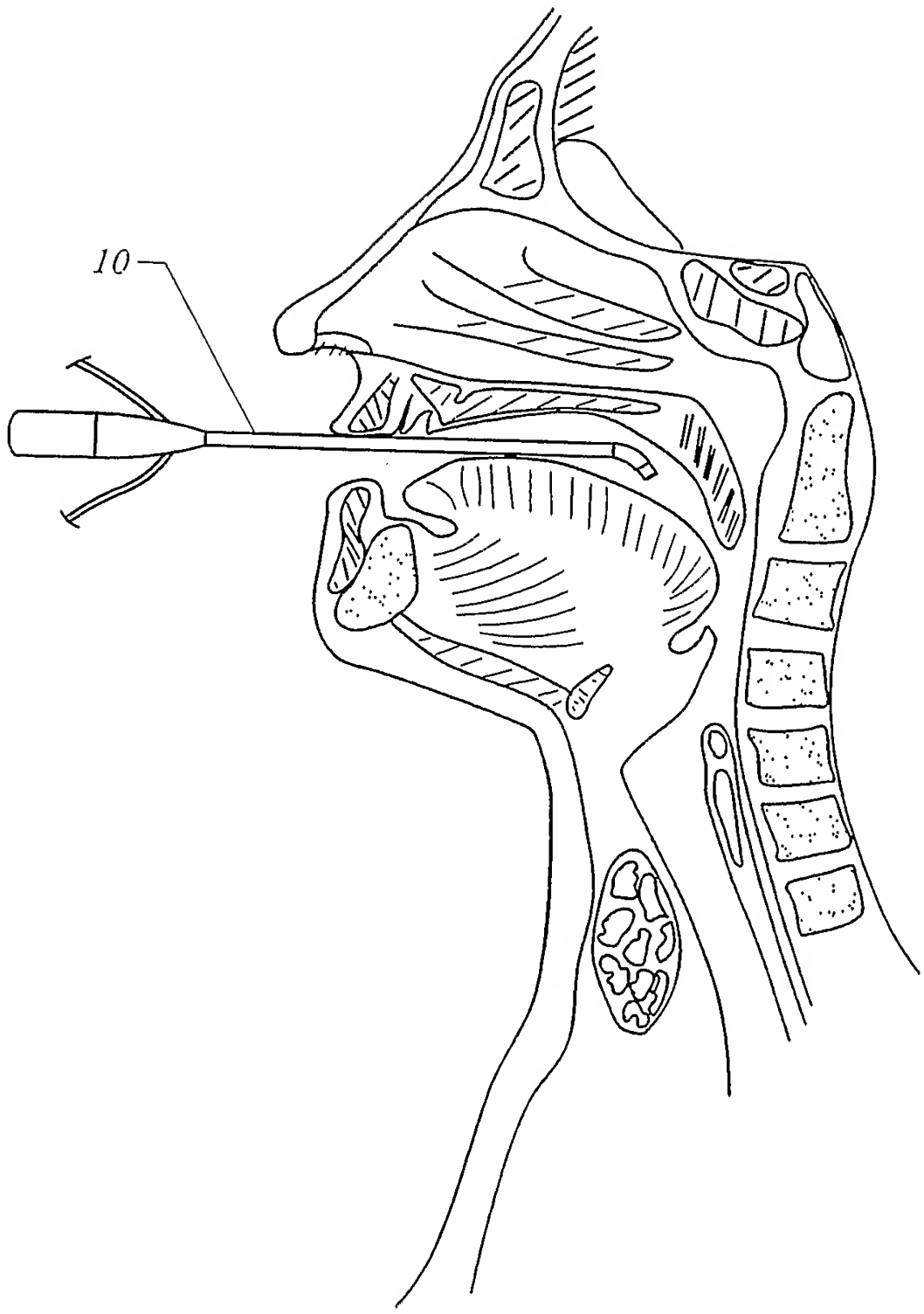

FIG. 2

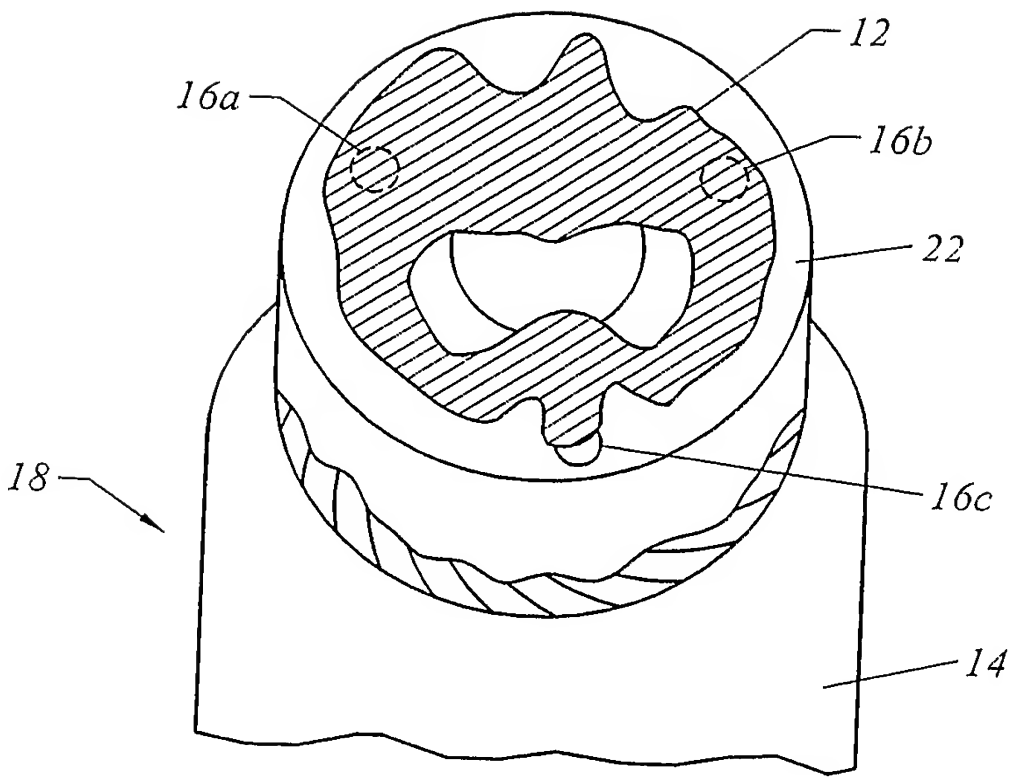

FIG. 3

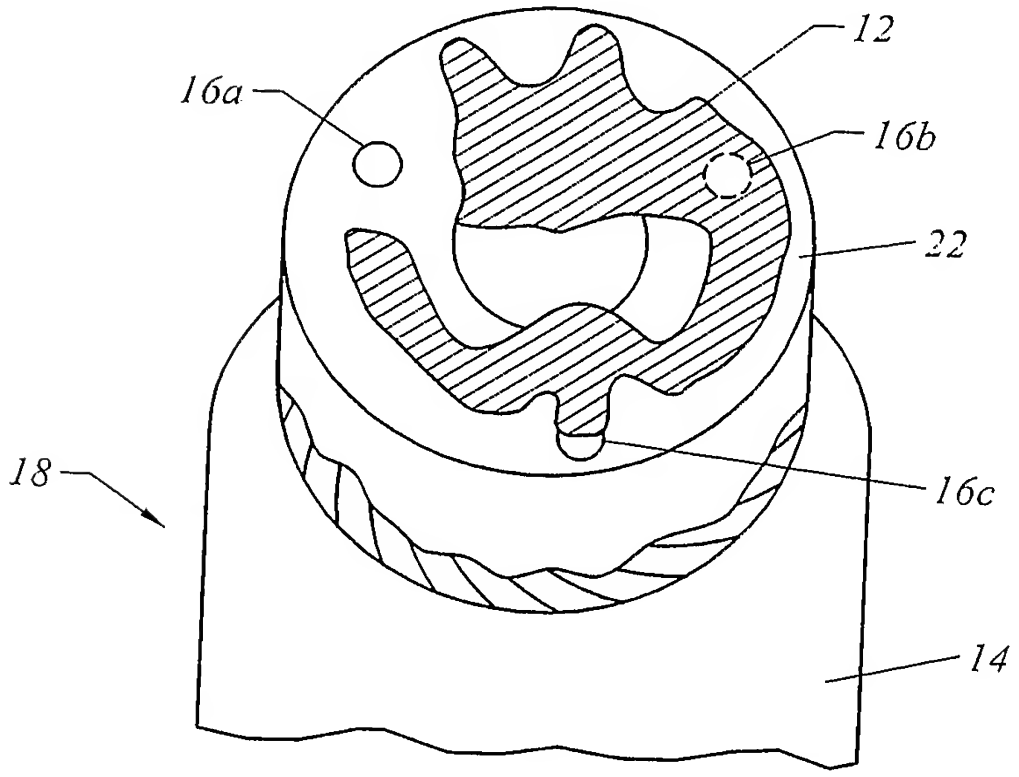

FIG. 4

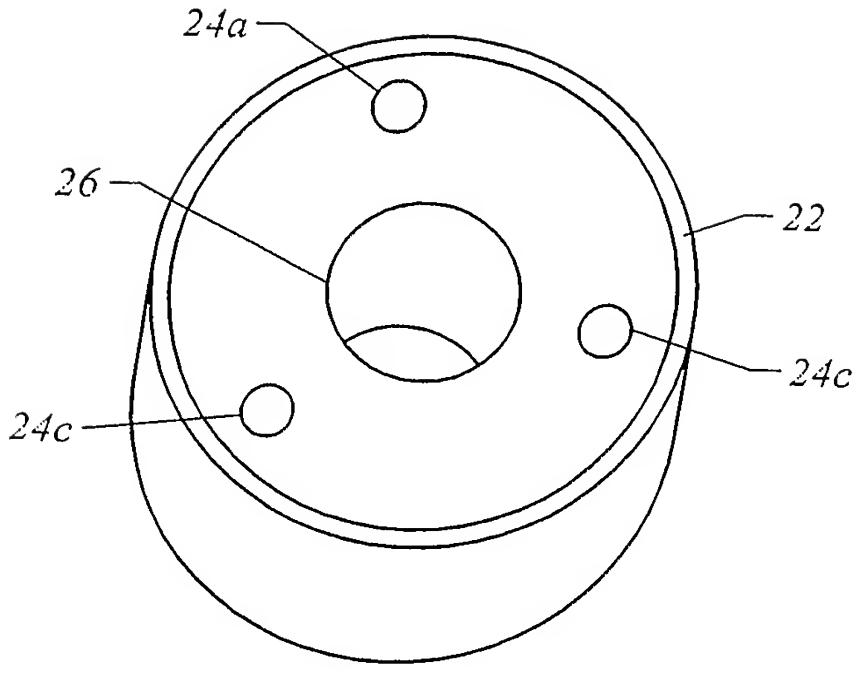

FIG. 5

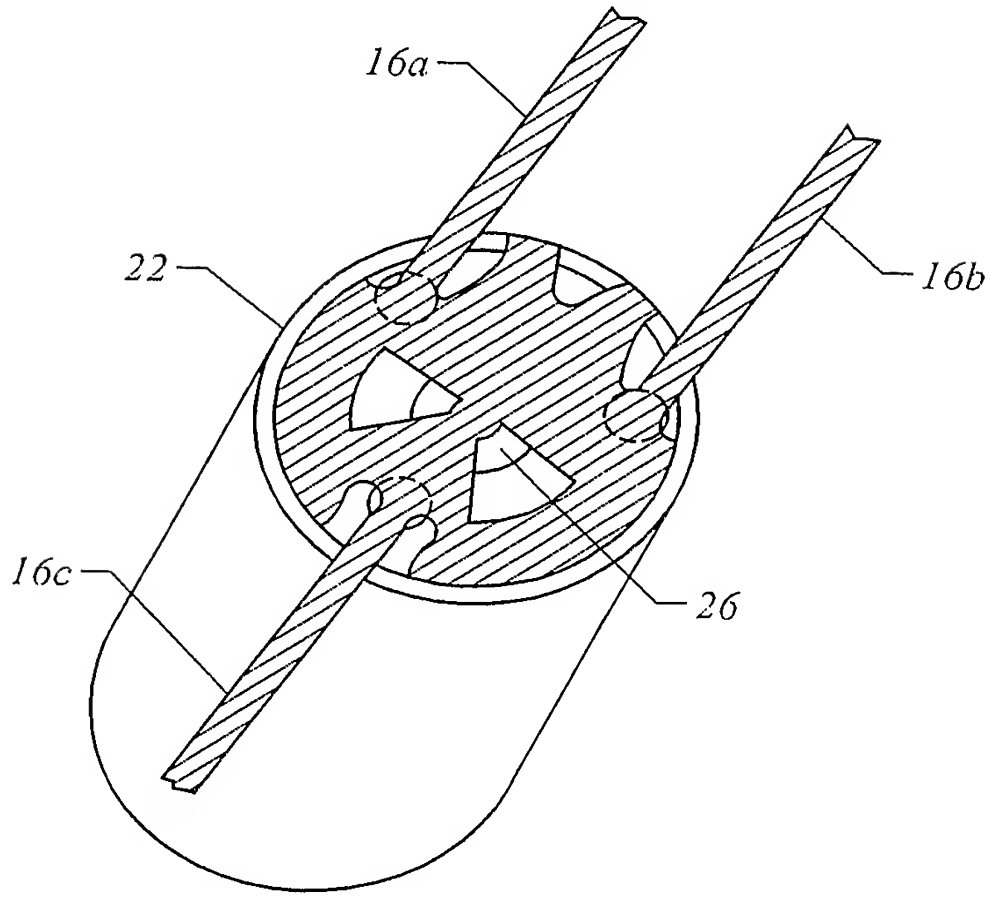

FIG. 6

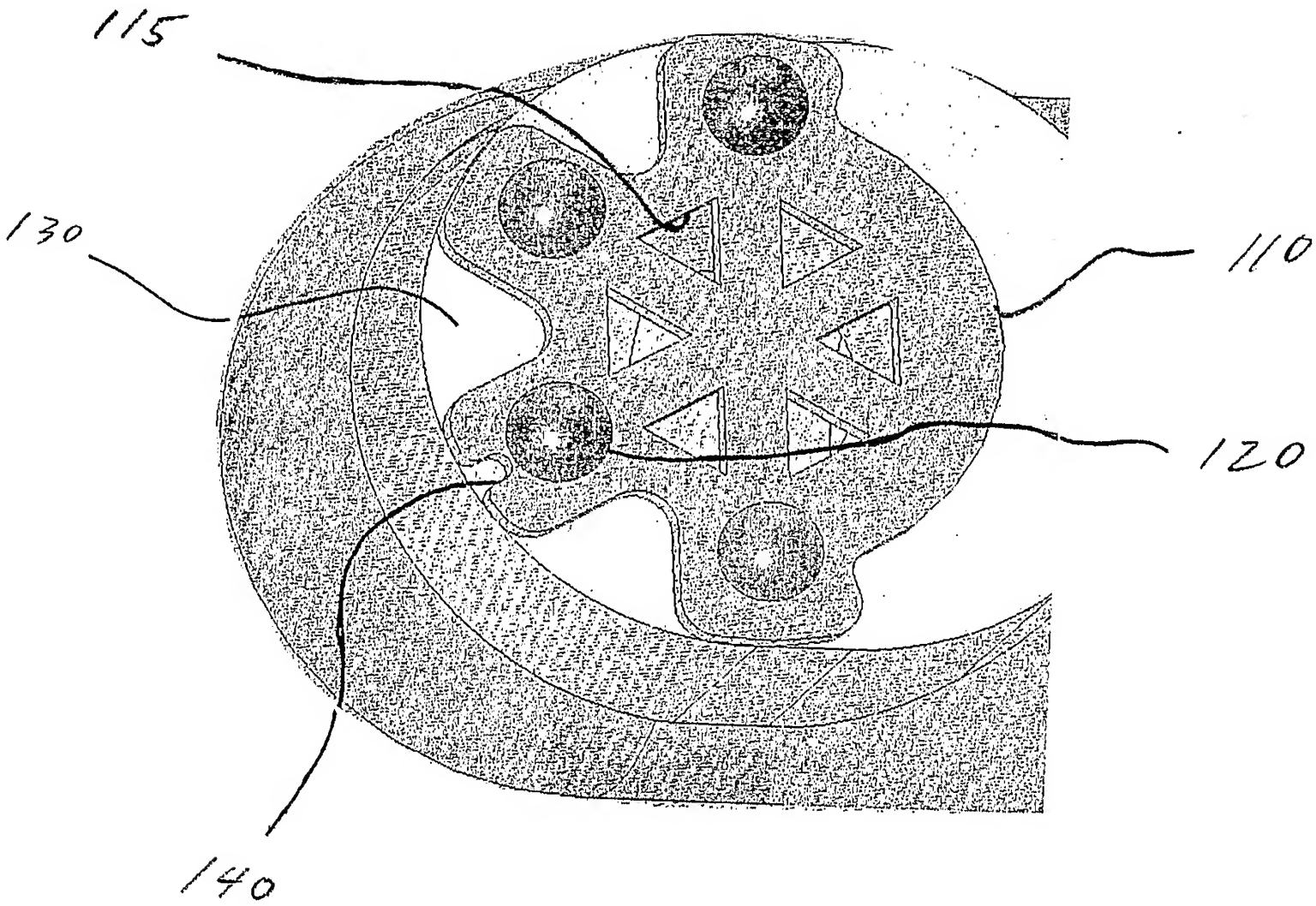

Fig. 7

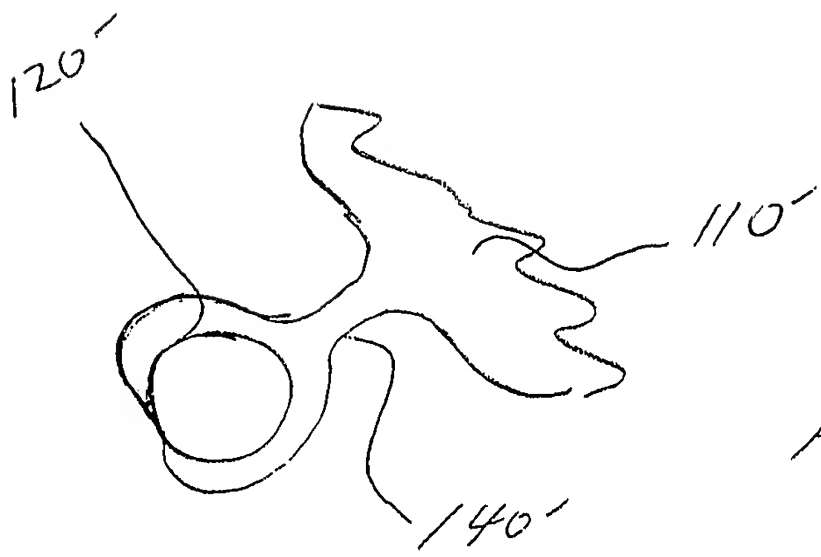

Fig. 7A